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(71) Applicant (for CA only): TELLMAN, Lars [SE/SE]; Kyrkogatan 6, S-239 40 Falsterbo (SE).
(71)(72) Applicant and Inventor: MEDOFF, Robert, J. [US/US]; 159 Ku'ukama Street, Kailua, HI 96734 (US).
(74) Agents: MAGNUSSON, Gustav et al.; Magnupatent AB, P.O. Box 6207, S-200 11 Malmö (SE).

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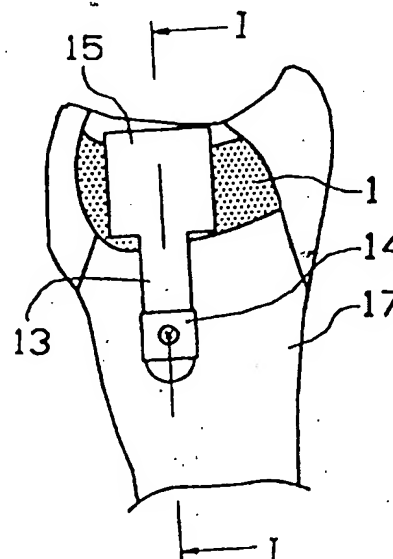
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(54) Title: GRAFT CONSTRAINT DEVICE

(57) Abstract

The present invention relates to a graft constraint device (10), having the main object of constraining graft material (1) packed into a bone defect or a space for buttressing an adjacent bone fragment. The graft material being autologous bone, allograft bone, xenograft, organic or inorganic material, "bone paste" or other similar materials. The graft constraint device (10) has a constraining end (12) and a fastening end (13), and is applied to a stable bone cortex with suitable fastening means (11).



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GRAFT CONSTRAINT DEVICE

- 5 The present invention relates to a means for constraining graft material according to the preamble of the independent claim.

Grafting materials, such as autologous bone, allograft bone, xenograft, organic or inorganic material or "bone paste", or other similar materials, are commonly used in procedures for fractures or surgical reconstruction of bones. These materials are used for two primary reasons -
10 (1) in order to promote bone healing as a biologic response, and (2) in order to provide structural support.

- 15 Intraarticular fractures are a common example of a situation in which grafting material can be used. In this situation, the primary role of the grafting material is to buttress and/or support bone fragments in an anatomic or functional position; in addition, the graft material may function to promote healing.

20 If the grafting material does not maintain its position at the site of application, several potential problems may occur. First and foremost is that the material no longer functions for its original and intended purpose. Migration of graft material may lead to migration of the fragment to be supported; this in turn may result in complications of joint
25 incongruity, arthritis, stiffness, pain, crepitation with joint motion, non-union or malunion, and secondary procedures (i.e. additional surgical procedures), to name a few.

- 30 In addition to losing intended function, migration of graft material may have additional deleterious effects. Migration of grafting material into adjacent soft tissues may initiate an inflammatory reaction or cause complications from mechanical pressure and irritation. For instance, graft material pressing on a nerve may cause nerve damage.
35 Graft material pressing on tendons may cause either fraying of the tendon (even rupture) or may cause scarring and limitation of tendon gliding. Migration of graft material into an adjacent joint can cause ar-

thrititis and joint damage. Moreover, the ability of grafting material to stimulate bone formation may cause problems if the graft migrates into the soft tissues. Occasionally, this may even stimulate formation of heterotopic bone in the soft tissues, which can cause scarring, stiffness, inflammation and pain.

The present invention addresses these problems by constraining the graft material at the site of application. For instance, one example of the present invention is to constrain graft material used with a commi-
10 nuted Colles' fracture. By maintaining the graft material at the original site of application, this invention avoids the complications associated with migration or drift of the graft material.

Thus, there is a need for a means to constrain graft material in its
15 intended position and to hinder the graft material from migration. This need is met by means of a device according to the characterizing part of claim 1.

Expedient embodiments of the present invention are disclosed in the de-
20 pendent claims.

The present invention will now be described in greater detail herein-
below, with the aid of embodiments shown in the drawings. In the accom-
panying drawings:

25 Figs.1 and 2 are side and top views, respectively, of a first embodiment of the invention, applied on the radius;

Fig. 3 is a top view, of a second embodiment of the invention;

30 Fig. 4 is a top view, of a third embodiment of the invention;

Figs.5 and 6 are side and top views, respectively, of a fourth embodi-
ment of the invention, applied on the radius; and

35 Figs.7 and 8 are cross-section views of optional plates used with the invention.

In this description the expression "constraining end" is used to indicate the part of the graft constraint device which actually constrains the graft material. The expression "fastening end" is used to indicate the part of the graft constraint device which receives the fastening means for securing the device to a stable bone cortex.

The first embodiment of the invention shown in Figs. 1 and 2 consists of a graft constraint device 10 having one constraining end 12 and one fastening end 13. The graft constraint device 10 is applied to a stable bone cortex of the radius 17 with fastening means. In this embodiment the fastening means is a screw 11 and a washer 14. In other embodiments the fastening means is only a screw, i.e. no washer is needed. The constraining end 12 of the graft constraint device 10 is formed into a plate 15 covering the opening into which the graft material 1 is inserted. In this embodiment and as viewed in Fig. 2 the plate 15 is broader than the fastening end 13. The size and design of the plate 15 is decided based on the conditions at the actual site of application, such as the positions and sizes of the fractures and fragments. Thus, in some embodiments the plate 15 may have the same width or even be narrower than the fastening end 13. At the outer end of the plate 15 pointed projections 16 are furnished for engagement with bone cortex. In another embodiment (not shown) the plate has no pointed projections. The graft constraint device 10 is secured to the radius 17 after the graft material has been placed. In a further embodiment (not shown) the plate has the form of a mesh or is furnished with multiple openings to allow ingrowth of blood vessels in the graft material.

Also in the second embodiment, shown in Fig. 3, the graft constraint device 20 has a fastening end 23 and a constraining end 22. The fastening end 23 is similar to the fastening end 13 of the first embodiment and has an opening 26 for receiving a fastening means. The constraining end 22 comprises malleable fingers 25, which allow contouring to the uneven anatomical site of application. The openings between the fingers 25 allow ingrowth of blood vessels into the grafting material.

In the third embodiment, shown in Fig. 4, the graft constraint device 30 is a wire bent into a U-shape. The diameter of the wire is preferably between 0.010" to 0.250". The base of the "U" forms the fastening end 33 and the upper part of the "fingers" 35 of the "U" forms the constraining end 32. This graft constraint device 30 is fastened at stable bone cortex by means of a screw 11 and washer 14. Also this embodiment is malleable enough to allow contouring to the actual site of application and allow ingrowth of blood vessels into the grafting material 1.

10 As an option, pointed projections cooperating with bone cortex are furnished at the outer ends of the fingers 35 of the graft constraint device 30 made of a wire bent into a U-shape. The pointed projections may be formed by bending the outer part of the wires 35. The site of the bend decides how far into, or even through, the graft the projections

15 will go.

As a further option a small plate (Figs. 7, 8) is placed between the extraosseous surface of the radius and the fingers 35 of the U. In this way the load of the graft constraint device is spread over a wider

20 area. In its most simple embodiment the plate 50 is a simple straight plate. In further embodiments the plate is furnished with means to constrain the plate from migrating. The means to constrain the plate from migrating have any suitable form such as the plate having a raised area 51 between the fingers 35 of the U, having two seats 52 for receiving

25 the fingers 35 of the U, or having two small holes placed near the distal edge of the plate to allow passage for the pointed projections of the bent fingers 35 of the U. If needed said plate is bent to conform to the dorsal surface.

30 The fourth embodiment shown in Figs. 5 and 6 is especially intended for use with synthetic graft materials. One example of such material is synthetic "bone paste" made by Norian Corp. The bone paste is injected into the osseous defect and allowed to harden. A graft constraint device according to the previous embodiments would constrain the material,

35 but would not prevent the graft material from displacing proximally within the bone itself. The graft constraint device 40 according to this embodiment is U-shaped with the base of the "U" forming the

fastening end 43. The fastening end 43 receives a screw 41 and washer 44 for securing the device to stable bone cortex. The constraint end 42 of the device 40 has the form of fingers 45 bent downward to project into the graft material 1. In use the fingers 45 are placed in the graft material while it is still soft. Then the synthetic graft material is allowed to harden around the fingers 45 projecting into the graft material.

In further embodiments (not shown) the constraining end is a combination of the above embodiment and one of the previous embodiments. Thus, it has several "fingers" of which at least one projects into the graft material and at least one lies over the graft material.

The graft constraint device is made thin and may in some embodiments be formed to follow the contour of the site of application, to minimize any discomfort for the patient. The graft constraint device is unobtrusive to avoid irritation of the adjacent soft tissue.

A person skilled in the art realizes that the graft constraint device, at the same time as being soft enough to contour, has sufficient stiffness for its intended purpose as a buttress.

In the embodiments shown in the figures screws with or without washers are used as fastening means. A person skilled in the art perceives that other fastening means may be used. Thus, in other embodiments pins, wires, blades, staples, brackets or indirect coaption with another device securely attached to the stable bone is used instead of screws to apply the device to a stable bone cortex.

As an option, pointed projections cooperating with bone cortex are furnished at the constraining end 12,22,32,42 of the graft constraint device 10,20,30,40 according to the different embodiments. The form of these pointed projections varies in that they may be pointed or not, and may be long enough to pass through a hole placed in the graft, such as a small hole drilled through a piece of cortical bone graft. Such an application would further constrain the graft material from slipping under the device.

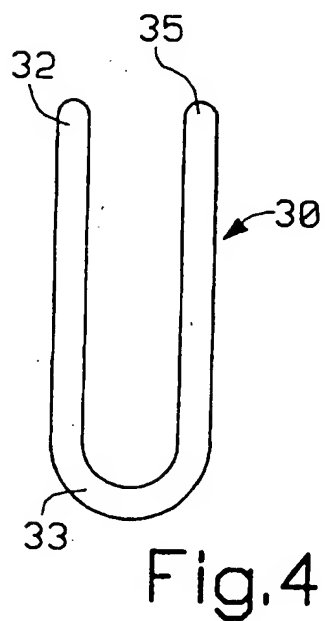
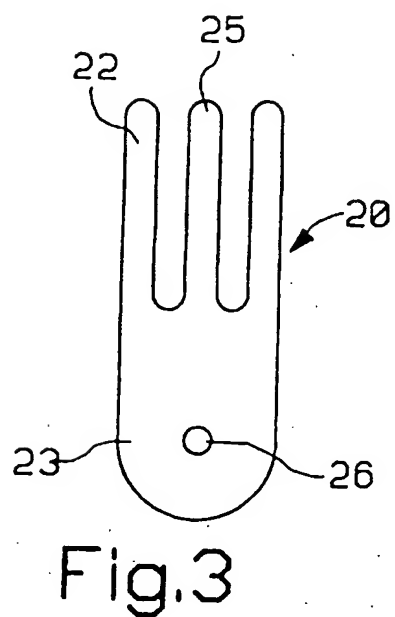
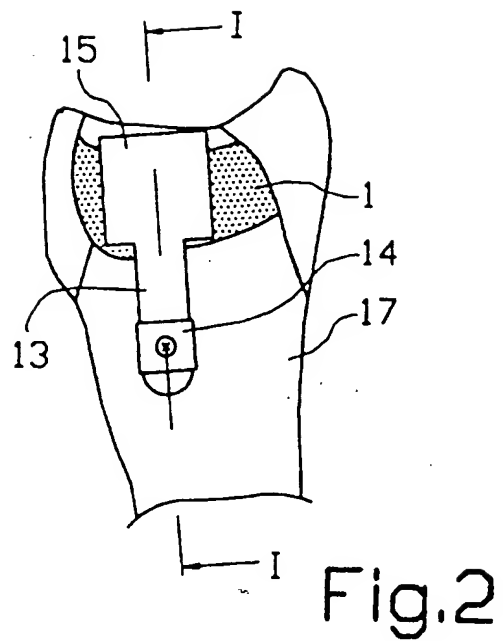
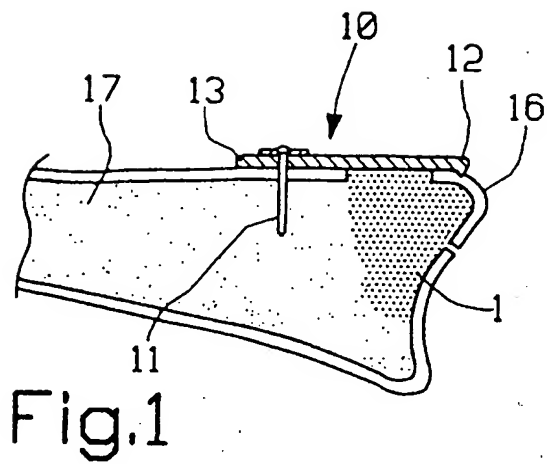
The above description has referred to but a limited number of embodiments of the present invention, but it will be readily perceived by a person skilled in the art that the present invention encompasses a
5 large number of embodiments without departing from the spirit and scope of the appended claims.

CLAIMS

1. A device (10,20,30,40) for constraining graft material (1) packed into a bone defect or a space for buttressing an adjacent bone fragment, characterized in that it has one end (12,22,32,42) for mainly constraining the graft material (1) and one end (13,23,33,43) for mainly receiving fastening means (11,14,41,44) for securing the device (10,20,30,40) to a stable bone cortex.
2. The device of Claim 1, characterized in that at least the end (12,22,32,42) for constraining the graft is malleable to allow contouring to the site of application and/or that the device has pointed projections (16) for cooperation with bone cortex.
3. The device of any of the preceding Claims, characterized in that the end (22,32,42) for constraining the graft (1) has one or more openings to allow ingrowth of blood vessels.
4. The device of any of the preceding Claims, characterized in that the constraining end has the form of a buttressing plate (15) covering at least a part of the graft material (1).
5. The device of any of Claims 1-3, characterized in that the constraining end has the form of a mesh.
6. The device of any of Claims 1-3, characterized in that the constraining end has the form of malleable fingers (25).
7. The device of any of Claims 1-3, characterized in that it is made of a wire (35) bent into a U-shape and/or that a plate is placed between the extraosseous surface of the bone and the constraining end (22,32).
8. The device of any of Claims 1-3 or 5-7, characterized in that the constraining end (45) is projecting into or through the graft material (1).

- 5 9. The device of any of Claims 1-3 or 5-8, c h a r a c t e r i z e d
in that a part of the constraining end is covering the graft mate-
rial (1) and that a part of the constraining end is projecting into
or through the graft material (1).
- 10 10. The device of any of the preceding Claims, c h a r a c t e r -
i z e d in that the fastening means are a screw (11,41) with or
without a washer (14,44).

1/2



2/2

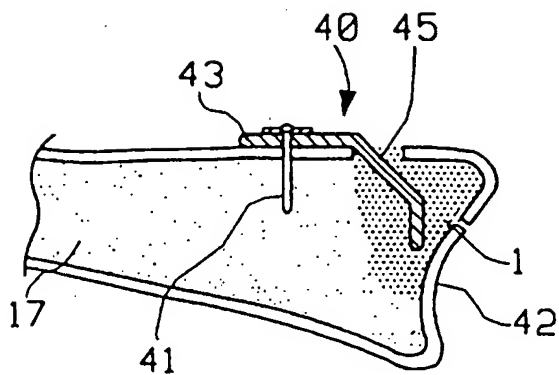


Fig.5

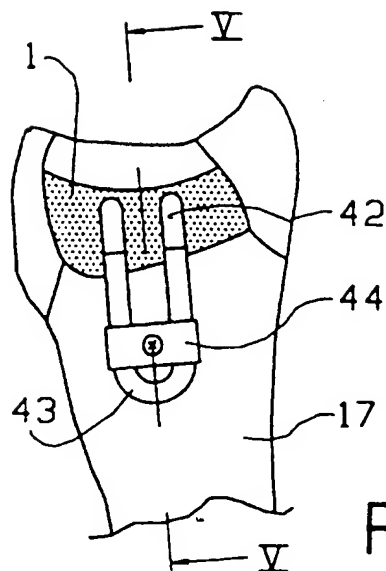


Fig.6

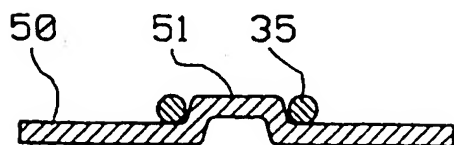


Fig.7

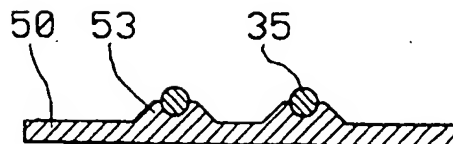


Fig.8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/00749

A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A61F 2/28, A61B 17/80 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC6: A61B, A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
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C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0609738 A1 (KIRSCH, AXEL), 10 August 1994 (10.08.94)	1,3-5,10
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PA	WO 9614802 A1 (KEHYAYAN, GEORGES ET AL.), 23 May 1996 (23.05.96), figures 6-8, abstract	1-4,8-10
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A	FR 2721195 A1 (AFRIAT JACQUES), 22 December 1995 (22.12.95), figure 2	1-2,8,10
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A	Derwent's abstract, No 86-111257/17, week 8617, ABSTRACT OF SU, 601851 (RIGA TRAUMATOLOGY), 15 November 1985 (15.11.85)	1-2,4
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Name and mailing address of the ISA: Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Leif Brander Telephone No. +46 8 782 25 00

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Information on patent family members

06/08/97

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